



UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 11 2009

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
www.uspto.gov

James V. Lilly  
Kagan Binder, PLLC  
221 Main St. North, Suite 200  
Stillwater, MN 55082

Re: Patent Term Extension  
Applications for  
U.S. Patent Nos. 5,258,028  
5,336,263  
5,571,182

Dear Mr. Lilly:

The USPTO is in receipt of your letter of March 5, 2009, relating to the status of the patent term extension applications filed in each of the above referenced patent numbers.

It is noted that 35 U.S.C. § 156 expressly states (in relevant part):

... the Secretary reviewing the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination and **shall publish in the Federal Register a notice of such determination.**

35 U.S.C. § 156(d)(2)(A)(ii) (emphasis added).

Please note that the statutory requirement of publication of FDA's determination of the regulatory review period in the Federal Register occurred on February 11, 2009 at 74 Fed. Reg. 6901. The Federal Register notice sets forth two time periods for public comment. Specifically, the 180-day period of 35 U.S.C. § 156(d)(2)(B)(i) (relating to submission of due diligence petitions) and the 60-day period provided for in 21 C.F.R. § 60.24 (relating to requests for revision of the regulatory review period determination).

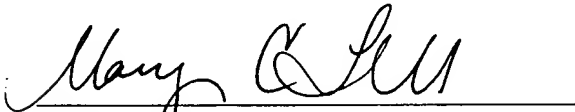
Action on the referenced patent term extension applications by the USPTO cannot occur until FDA has made their final determination with respect to the regulatory review period as published in the Federal Register of February 11, 2009, after which FDA will communicate their findings to the USPTO. Please note that the first time period concludes on April 13, 2009, and the second time period concludes on August 10, 2009. Thus, Applicant's letter of March 5, 2009, stating, "we have received no word from the United States Patent and Trademark Office concerning these petitions" is premature. Applicant may wish to review MPEP sections 2756 and 2757 relating to correspondence between the USPTO and the regulating agency and the duties of the regulatory agency under 35 U.S.C. § 156.

Any further correspondence with respect to this matter should be addressed as follows:

By mail:                      Mail Stop Hatch-Waxman PTE  
                                    P.O. Box 1450  
                                    Alexandria, VA 22313-1450

By FAX:                      (571) 273-0100

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755. E-mail inquiries should be directed to [mary.till@uspto.gov](mailto:mary.till@uspto.gov).



Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc:      Office of Regulatory Policy  
         Food and Drug Administration  
         10903 New Hampshire Ave.  
         Bldg. 51, Rm. 6222  
         Silver Spring, MD 20993-0002

RE: Macroplastique® Implants  
FDA Docket Nos.:    FDA-2008-E-0091  
                                 FDA-2008-E-0099  
                                 FDA-2008-E-0204

Attention: Beverly Friedman